UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/941,682	08/30/2001	Christian Mayaud	47777-0009	9565

53437 7590 11/28/2007

ROBERT M. SCHWARTZ, P.A.
P.O. BOX 221470
HOLLYWOOD, FL 33022

EXAMINER	
PORTER, RACHEL L	

ART UNIT	PAPER NUMBER
3626	

MAIL DATE	DELIVERY MODE
11/28/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/941,682	MAYAUD, CHRISTIAN	
	Examiner	Art Unit	
	Rachel L. Porter	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 April 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *97-123* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *97-123* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Notice to Applicant

1. This communication is in response to the amendment filed 4/30/07. Claims 97-123 are pending.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 119-120 rejected under 35 U.S.C. 102(b) as being anticipated by Renvall (WO 91/02447).

[Claim 119] Renvall discloses a method for aggregating electronic prescription data, comprising the steps of:

- electronically storing at least a first patient record including at least one prescribed drug selected from a list of drugs (approved by a drugs benefit provider) and a prescriber identifier representing the user that selected the at least one prescribed drug; (Figure 2, page 5, lines 21-27; pages 7, line 28-page 8, line 5)
- electronically storing at least a second patient record including at least one prescribed drug selected from a list of drugs (approved by a drugs benefit

provider) and a prescriber identifier representing the user that selected the at least one prescribed drug; (pages 7, line 28-page 8, line 5-- The doctor makes his/her rounds with multiple patients scanning their health conditions, storing this information in a barcode reader.)

- aggregating data from the at least a first patient record with data from the at least a second data patient record to form an aggregated data record; and (pages 7, line 28-page 8, line 5-- The doctor makes his/her rounds with multiple patients scanning their health conditions, storing this information in a barcode reader.)
- outputting the aggregated data record. (pages 7, line 28-page 8, line 5--Then this information is also registered from the barcode device to a PC, also Rx's can be written)

***As per the recitation of "approved by a drugs benefits provider in the present claim", the recited method does not include a step approving drugs, only scanning or entering the medications from the compiled list of drugs. Thus, the manner of forming the drug list (i.e. approved by drug benefit provider) is not pertinent. It should be noted that only the components from the system which affect the resultant function of the system, or data in the method, which affects the outcome of the method will be given patentable weight and have art applied accordingly.

[Claim 120] Renvall discloses the method of claim 119, wherein:

- each of the at least a first patient record and the at least a second patient record additionally includes at least one patient condition associated with the at least

one prescribed drug selected from a list and at least one prescriber identifier representing the user that selected the at least one prescribed drug; and (Figure 2; page 7, lines 28-page 8, line 5—medication of patient, state of health, name of doctor—all linked with one another)t

- the aggregated data record includes at least a selected drug, its associated patient condition and its associated prescriber identifier for each patient data record. pages 7, line 28-page 8, line 5-- The doctor makes his/her rounds with multiple patients scanning their health conditions, storing this information in a barcode reader.)

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 121-122 are rejected under 35 U.S.C. 103(a) as being unpatentable over Renvall.

[Claims 121-122] Renvall discloses the method of claim 119 as explained in the rejection of claim 119. Renvall further discloses providing a report (i.e. output) that includes the prescriber information/ identifier(Figure 2). Renvall does not expressly

disclose sorting the aggregated report by particular parameters. However, at the time of the applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the system and method of Renvall to provide aggregated reports which could be sorted by various parameters, including medication, patient name, date, and prescriber. One would have been motivated to include this feature to provide a system and method that is adaptable to the preferences and demands of the healthcare providers who use it.

6. Claim 123 is rejected under 35 U.S.C. 103(a) as being unpatentable over Renvall in view of Official Notice (as substantiated by "Big Brother-Is He Here?" –Anonymous) [Claim 123]] Renvall teaches the method of claim 119 as explained in the rejection of claim 119, but does not expressly disclose the step of selling information derived from the aggregated data. However, gathering customer and selling "lead" data is old and well known in the art. For example, the "Big Brother" reference discloses that "vast amounts of personal knowledge" were routinely collected and stored in private databanks (par. 6) and that "private organizations compiled records of drug testing; social science screening ...computerized medical records..." (par. 7-8) The reference further discusses "information vendors" and the collection of customer data to be used and sold to third parties and the customer's ability to opt out of such programs. (par. 11-13) At the time of the applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the method of Renvall to take information derived from the aggregated records and sell this information (e.g. to pharmaceutical companies).

One would have been motivated to include this feature to increase the marketability of the system and to help offset certain costs associated in setting up the system.

7. Claims 97-106 and 114-118 are rejected under 35 U.S.C. 103(a) as being unpatentable over Renvall (WO 91/02447) in view of Brown et al ("A computerized prescription writing Program for program for Doctors" and Doyle, Jr. (USPN 5,070,452) [Claim 97] Renvall discloses a computer-implemented method for assembling a prescription, the method comprising:

- providing an electronic database of drugs; (Renvall: page 5, line 37- page 6, line 15-alphanumeric designations are assigned to diagnoses, types of care...**medicines.** All bar codes and corresponding information are collected in catalogues and in the memory or computers of the information handling system. In each country a central database with all the barcodes and corresponding information is provided.)
- electronically storing a patient identifier in a computer memory medium; (pg. 7, line 28-pg. 8, line 5)
- electronically associating with the patient identifier a drug selected from a list of drugs; (Figure 2, page 5, lines 21-27) Claim 123 are rejected under 35 U.S.C. 103(a) as being unpatentable over Renvall in view of Official Notice (as substantiated by "Big Brother-Is He Here?" –Anonymous)/
- electronically associating a dosage for the selected drug, with the patient identifier and the selected drug; and (Figure 2: patient name and dosage)

- retrieving and outputting the associated selected drug and dosage associated with a patient identifier. (Fig. 2; page 7, lines 28-34, page 8, 27-34)

Claim 97 has been amended to recite:

- electronically identifying from the database of drugs, a list of drugs approved by a drugs benefit provider for the patient associated with the patient identifier.

Renvall does not expressly disclose electronically identifying a list of drugs from the drug database. Brown discloses electronically identifying a list of drugs/ subset of drugs from a drug database. (pg. 101: par. 1-3; pg. 102, par. 7) At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to electronically identify a subset or list of drugs from a drug database when providing a prescription. As suggested by Brown, one would have been motivated to include this feature to speed the prescription writing process, accessing a personal drug formulary which is appropriately indexed. (page 101: summary, par. 3; page 19, par. 18)

Renvall and Brown do not expressly disclose that the list of drug is approved by a drugs benefits provider. However, it is well-known to electronically notify healthcare providers whether particular treatments are approved by a healthcare benefit provider for a patient associated with a patient identifier, as evidenced by Doyle. (col. 2, lines 45-56; col. 4, line 54-62; col. 5, lines 56-64). At the time of the applicant's invention, it would have been obvious to one of ordinary skill in the art to combine the teachings of Doyle with the method of Renvall in view of Brown to electronically identify a list of treatments (e.g. drugs) that are approved by a benefits provider for a patient associated

with the patient identifier. As suggested by Doyle, one would have been motivated to include this feature to facilitate the claims adjudication process for the health care provider and payer. (col. 2, lines 4-25)

[Claim 98] Renvall discloses the method of claim 97, additionally comprising a patient condition, converted to electronic data and electronically identified by the patient identifier, the selected drug being chosen based on the patient condition. (page 7, lines 28-34: Doctor scans patient's state of health, then generates prescription with treatment/ with medication)

[Claim 99] Renvall discloses the method of claim 97, further including the steps of: aggregating at least a portion of the assembled prescription data associated with multiple patient identifiers; and storing the aggregated prescription data. (pages 7, line 28-page 8, line 5)

[Claim 100] Renvall discloses the method of claim 98, further including the steps of: electronically associating with each drug selected from a list and with the patient condition for which the drug was selected, a prescriber identifier representing the user that selected the drug; and (pages 7, line 28-page 8, line 5)

aggregating data records for multiple patient identifiers, each data record including at least a selected drug, its associated patient condition and the associated prescriber identifier. (pages 7, line 28-page 8, line 5)

The doctor makes his/her rounds with multiple patients scanning their health conditions, storing this information in a barcode reader. Then this information is also registered in a PC.

[Claim 101] Renvall discloses a method for assembling an electronic prescription, comprising the steps of:

- providing an electronic database of drugs; (Renvall: page 5, line 37- page 6, line 15-alphanumeric designations are assigned to diagnoses, types of care...**medicines.** All bar codes and corresponding information are collected in catalogues and in the memory or computers of the information handling system. In each country a central database with all the barcodes and corresponding information is provided.)
- electronically obtaining a patient identifier converted to electronic data; (page 7, lines 28-31, human and barcode format)
- electronically retrieving a dosage for the at least one prescribed drug associated with the at least one prescribed drug and the patient identifier; (page 7, lines 31-35—information registered with state of health and medication, and patient personal identifier data)
- storing the at least one prescribed drug, the dosage and the patient identifier in an electronic memory; and (page 7, lines 31-35: registered with state of health and medication, and patient personal identifier data)

- outputting at least the at least one prescribed drug. (Figure 2; page 8, line 31-page 9, line 3)

Claim 101 has been amended to further recite:

- electronically retrieving from the database of drugs a list of drugs approved by a drugs benefit provider for the patient associated with the patient identifier, and the identity of at least one prescribed drug associated with the patient identifier, the at least one prescribed drug being selected from a list of drugs approved by a drugs benefit provider

Renvall discloses a method comprising electronically retrieving the identity of at least one prescribed drug associated with the patient identifier, the at least one prescribed drug being selected from a list of drugs; (Figure 2, page 5, lines 21-27; page 7, lines 31-35; page 9, lines 1-3)

Renvall does not expressly disclose electronically retrieving a list of drugs from a drug database. Brown discloses electronically retrieving a list of drugs/subset of drugs from a drug database. (pg. 101: par. 1-3; pg. 102, par. 7) At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to electronically identify and retrieve a subset or list of drugs from a drug database when providing a prescription. As suggested by Brown, one would have been motivated to include this feature to speed the prescription writing process, accessing a personal drug formulary which is appropriately indexed. (page 101: summary, par. 3; page 19, par. 18)

Renvall and Brown do not expressly disclose that the list of drug is approved by a drugs benefits provider. However, it is well-known to electronically notify healthcare providers whether particular treatments are approved by a healthcare benefit provider for a patient associated with a patient identifier, as evidenced by Doyle. (col. 2, lines 45-56; col. 4, line 54-62; col. 5, lines 56-64). At the time of the applicant's invention, it would have been obvious to one of ordinary skill in the art to combine the teachings of Doyle with the method of Renvall in view of Brown to electronically identify a list of treatments (e.g. drugs) that are approved by a benefits provider for a patient associated with the patient identifier. As suggested by Doyle, one would have been motivated to include this feature to facilitate the claims adjudication process for the health care provider and payer. (col. 2, lines 4-25)

[Claims 102-105] Renvall discloses the method of claim 101, further including the step of electronically associating a patient condition, converted to electronic data with the patient identifier, the prescribed drug being selected based on the patient condition. (page 7, lines 28-34). The patient's history record includes prescribed drug and dosage information (Figure 2) and patient condition (i.e. state of health).

[Claim 106] Renvall discloses a method further comprises storing patient data in an electronic memory, as explained in the rejection claim 101. Renvall further discloses that the memory is part of a source-oriented data-retrieval subsystem, the data retrieval subsystem being connectable to access at least one data-retrieval network to retrieve source prescribing information and patient-related data to the point-of-care from at least

one remote source database. (page 7, lines 2-4; 28-page 8, line 5; col. 10, lines 20-25—networking)

[Claims 114-116] Renvall discloses a system and method further including the steps of defining a prescription expiration routine including dosing, amount and expiration drug quantifiers and including system calculation of a relationship between the drug quantifiers. (Figure 2); selectively storing the electronic prescription in local storage, in remote storage and in remote file transfer (page 8, lines 21-33); and further including the step of transmitting the electronic prescription across a network for fulfillment by a specified pharmacy. (page 8, lines 31-33).

[Claim 117] Renvall discloses the method of claim 101, further including the steps of: aggregating at least a portion of the assembled prescription data associated with multiple patient identifiers; (Figure 2; page 7, lines 28-page 8, line 5) and storing the aggregated prescription data. (page 7, lines 34 -page 8, line 5)

[Claim 118] Renvall discloses the method of claim 101, further including the steps of:

- electronically associating with each drug selected from a list and with the patient condition for which the drug was selected, a prescriber identifier representing the user that selected the drug; and (Figure 2; page 7, lines 28-page 8, line 5—medication of patient, state of health, name of doctor—all associated with one another)

- aggregating data records for multiple patient-identifiers, each data record including at least a selected drug, its associated patient condition and the associated prescriber identifier.(page 7, lines 34 -page 8, line 5)

8. Claim 107 rejected under 35 U.S.C. 103(a) as being unpatentable over Renvall, Brown, and Doyle, as applied to claim 101 and in further view of Howson (USPN 5,088,981)

[Claim 107] Renvall teaches the method of claim 101, but does not expressly disclose electronically associating the patient record with allergies or drug interactions. Howson discloses a system/method wherein the patient information is electronically associated with drug interaction information/allergies. (col. 7, lines 5-30; col. 16, lines 36-40) The system method is equipped to look up drug dosage/proper prescription information, check for drug interactions and update the patient's records accordingly. At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the system/method of Renvall with the teaching of how to include information on drug interactions or allergies. One would have been motivated to include this feature to include information to ensure the safety and health of the patient receiving the prescription. (Howson: col. 1, lines 17-21)

9. Claims 108-112 rejected under 35 U.S.C. 103(a) as being unpatentable over Renvall, Brown and Doyle, as applied to claims 101 and 103 and in further view of "Data Hard to Get, Has Many Applications" (Anonymous).

[Claims 108-110] Renvall, Brown, and Doyle disclose a method for assembling an electronic prescription as explained in the rejection of claim 101. Renvall further discloses displaying the patient record (page 8, lines 22-24), but does not expressly disclose assembling the patient records from multiple databases, and issuing a drug benefit plan with preferred drug formularies to the patient. "Data Hard to Get..." discloses a system and method wherein patient data and drug formulary data is assembled from a plurality of sources/databases (page 4, par. 22-25) and wherein drug formulary data, including preferred drugs for a condition are provided (par. 24-25). At the time of the Applicant's invention it would have been obvious to one of ordinary skill in the art to modify the system/method of Renvall with the teaching of "Data Hard to Get...". As suggested by the article, one would have been motivated to include these features to facilitate benefits management and to ascertain the appropriateness of a treatment. (par. 25).

[Claim 111] Renvall, Brown, and Doyle disclose a method for assembling an electronic prescription as explained in the rejection of claim 101. Renvall further discloses a system and method for accessing patient drug information, (page 7, lines 28-34), and patient drug selection(page 8, lines 22-27) but does not disclose accessing remote database get formulary information. "Data Hard to Get..." discloses a system and method wherein patient data and drug formulary data is assembled from a plurality of sources/databases (page 4, par. 22-25) and wherein drug formulary data, including preferred drugs for a condition are provided (par. 24-25). At the time of the Applicant's

invention it would have been obvious to one of ordinary skill in the art to modify the system/method of Renvall with the teaching of "Data Hard to Get...". As suggested by the article, one would have been motivated to include these features to facilitate benefits management and to ascertain the appropriateness of a treatment. (par. 25).

[Claim 112] Renvall discloses the method of claim 101 as explained in the rejection of claim 101, but does not describe providing information on formulary guidelines. "Data Hard to Get..." discloses a system and method wherein patient data and drug formulary data is provided from a plurality of sources/databases (page 4, par. 22-25) and wherein drug formulary data, including preferred drugs for a condition are provided (par. 24-25). At the time of the Applicant's invention it would have been obvious to one of ordinary skill in the art to modify the system/method of Renvall with the teaching of "Data Hard to Get...". As suggested by the article, one would have been motivated to include these features to facilitate benefits management and to ascertain the appropriateness of a treatment. (par. 25).

10. Claims 113 is rejected under 35 U.S.C. 103(a) as being unpatentable over Renvall, Brown, and Doyle and in further view of Official Notice (as substantiated by Howson-US 5,070,452)

[Claim 113] Renvall teaches the method of claim 101 as explained in the rejection of claim 101, but does not expressly disclose logging information regarding 3rd party access. Renvall does disclose protecting patient data (page 8, lines 3-5). Moreover,

the use of audit trails for data access is well known in the art. For example, Howson discloses information regarding patient treatment time, date is gathered for audit trail purposes. Furthermore, any access to the patient's record must be signed off on and is made a permanent part of that patient's record. (col. 16, lines 6-46) At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the system/method of Renvall to include an audit trail feature, with the motivation of ensuring patient information is closely monitored (page 9, lines 27-30)

Response to Arguments

11. Applicant's arguments with respect to claims 97-118 have been considered but are moot in view of the new ground(s) of rejection.

12. Applicant's arguments filed 4/30/07 have been fully considered but they are not persuasive.

(A) Applicant argues that Howson does not teach the limitations of claim 107.

In response, the Examiner respectfully disagrees. Claim recites "electronically associating the patient identifier with the drug interaction information/ allergies. " Howson discloses a system/method wherein the patient information is electronically associated with drug interaction information/allergies. (col. 7, lines 5-30; col. 16, lines 36-40) The system method is equipped to look up drug dosage/proper prescription information, check for drug interactions and update the patient's records accordingly.

(B) Applicant's challenges Examiner's use of official notice in the rejection of claims 113, and 123.

In response the Examiner has provided references to substantiate the noted facts.

Conclusion

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rachel L. Porter whose telephone number is (571) 272-6775. The examiner can normally be reached on M-F, 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on (571) 272-6776. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RP

C. LUKE GILLIGAN
PRIMARY EXAMINER
TECHNOLOGY CENTER 3600